Medical Device Alert

MDA/2017/035    Issued: 19 December 2017 at 14:00    Valid until: Dec 2018

Nasogastric (NG) feeding tubes – recall due to risk of neonatal or paediatric patient choking on ENFIT connector cap

Summary
Manufactured by Maxter Catheters – patients could accidentally pull off the connector cap and choke on it.

Action

- Return all unused, affected devices to the manufacturer – product codes of affected stock are listed in the Field Safety Notice (FSN).
- Ensure relevant healthcare professionals are aware of the FSN.
- Follow the FSN actions for managing patients with these NG tubes.
- Fill in the acknowledgement form in Annex 1 of the FSN and return it to the manufacturer.

Action by
All staff who use the affected devices

Deadlines for actions
Actions underway: 22 January 2018
Actions complete: 20 April 2018
Manufacturer contacts

Maxter Catheters/Halyard Health
Tel: +33 491 467 305, +32 2 711 27 19
Email: RA.EMEA@hyh.com or Camille.chavy@hyh.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Community children’s nurses
- Dietetics departments
- Dieticians
- District nurses
- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- Health visitors
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nutrition nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:

- Nutritional nurse specialists
Social services
Liaison officers for onward distribution to all relevant staff including:
• Children’s disability services

Independent distribution

Establishments registered with OFSTED
• Children’s services
• Educational establishments with beds for children
• Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health’s Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number MDA/2017/035 or 2017/010/023/701/012.

Technical aspects
Rebecca Flint or Jenifer Hannon, MHRA
Tel: 020 3080 6083 / 7153
Email: Rebecca.flint@mhra.gov.uk or Jenifer.Hannon@MHRA.gov.uk

Clinical aspects
Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:
Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.
Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland
Tel: 0131 275 7575
Email: nss.iric@nhs.net

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<td>Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.</td>
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<td>Private facilities providing care to private clients report to the Care Inspectorate and MHRA.</td>
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Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government
Tel: 02920 823 624 / 02920 825 510
Email: Haz-Aic@wales.gsi.gov.uk

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MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health
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